# HbA1c verlaging voorafgaand aan een operatie

Gepubliceerd: 12-04-2017 Laatst bijgewerkt: 15-05-2024

Preoperative HbA1c values are related to the risk of postoperative complications and mortality in patients with diabetes mellitus (DM). Therefore, the effect of preoperative HbA1c lowering on postoperative complications in poorly regulated diabetes...

| | |
|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON29027

**Bron**
Nationaal Trial Register

**Verkorte titel**
The HALT study

**Aandoening**

Diabetes mellitus
Surgery
Anaesthesia
HbA1c

### Ondersteuning

**Primaire sponsor:** Academic Medical Centre, Amsterdam
**Overige ondersteuning:** self-financing research

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

The main outcome parameter is whether it is possible to lower HbA1c > 1mmol/mol in the participating subjects or not.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Rationale: Preoperative HbA1c values are related to the risk of postoperative complications and mortality in patients with diabetes mellitus (DM). Therefore, the effect of preoperative HbA1c lowering on postoperative complications in poorly regulated diabetes mellitus (DM) patients should be evaluated. However, until now it is unknown whether it is possible at all to lower HbA1c in patients awaiting elective surgery.

Objective: To study the feasibility of lowering HbA1c before elective surgery in patients with suboptimally controlled DM (HbA1c >53 mmol/mol).

Study design: We will perform a single-centre open label pilot trial.

Study population: Fifteen adult patients (18-80) with poorly regulated DM type 2, scheduled for elective surgery.

Intervention: All participating subjects will be referred to the in-hospital diabetes nurse (IHDN) for optimisation of their DM treatment.

Main study parameters/endpoints: The main outcome parameter is the proportion of patients in which HbA1c lowering is successful (ie > 10 mmol/mol decrease inclusion-surgery or HbA1c before surgery <53 mmol/mol), comparing HbA1c at inclusion (during pre-assessment) with HbA1c on the day of surgery.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Risk associated with this study is comparable to routinely optimizing diabetes care and thereby lowering HbA1c in the outpatient setting. The main risk is hypoglycaemia, and this will be prevented as much as possible in clinical practice. Possible benefit is improvement of diabetes regulation and reduction in postoperative complications. In general, this study will be the first step towards a randomized controlled trial, studying the possible benefits of lowering postoperative complications in patients with DM.

### Doel van het onderzoek

Preoperative HbA1c values are related to the risk of postoperative complications and mortality in patients with diabetes mellitus (DM). Therefore, the effect of preoperative HbA1c lowering on postoperative complications in poorly regulated diabetes mellitus (DM) patients should be evaluated. However, until now it is unknown whether it is possible at all to lower HbA1c in patients awaiting elective surgery within a short time period.

Therefore the objective of this project is to study the feasibility of lowering HbA1c before elective surgery in patients with poorly controlled DM (HbA1c >7%/53 mmol/mol).

**Onderzoeksopzet**

Screening

Patients with DM presenting at the outpatient anaesthesiology pre-assessment clinic will be asked to participate in the study. As standard clinical procedure, blood will be drawn for HbA1c determination for all patients with DM scheduled for surgery. Based on the outcome, patients that have an HbA1c >7% (53 mmol/mol) and are willing to participate will be contacted by the IHDN.

Intervention

The IHDN will evaluate the current DM treatment in a first phone contact. The IHDN will provide a treatment advice to optimise the current treatment, if necessary in cooperation with the patient's primary care physician or other care providers treating the patient for DM. Follow-up and outpatient visits will be planned if deemed necessary by the IHDN. Optimisation of therapy is patient dependent, but will be performed according to the NHG standard and AMC diabetes protocols.

Day of surgery

Blood will be drawn for HbA1c determination on the day of surgery. A fasting fingerstick glucose measurement is performed.

**Onderzoeksproduct en/of interventie**

Patients willing to participate and meeting the in- and exclusion criteria will be referred to the in-hospital diabetes nurse (IHDN). The IHDN will contact the patient by phone and evaluate the current DM treatment. The IHDN will provide a treatment advice to optimise the current treatment, if necessary in cooperation with the patient's primary care physician. Follow-up and outpatient visits will be planned if deemed necessary by the IHDN. Optimisation of therapy is patient depending, but will be performed according to the NHG standard and AMC diabetes protocols. The IHDN is supervised by prof. dr. J.H. DeVries, endocrinologist involved in this study. On the day of surgery, blood will be drawn for a final HbA1c determination.

# Contactpersonen

### Publiek

J. Hermanides
Amsterdam
The Netherlands
0031-205669111

### Wetenschappelijk

J. Hermanides
Amsterdam
The Netherlands
0031-205669111

## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Diagnosis of DM type 2 at least 3 months prior to the screening

- Adult patients, age 18-80 years inclusive

- HbA1c >7% (53 mmol/mol) as measured at the pre-assessment clinic

- Scheduled for elective surgery

- Willing and able to provide written informed consent

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Emergency surgery or scheduled surgery < 3 weeks

- Palliative oncological surgery

- Underlying condition that does not allow patients to participate in the study

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-06-2017 |
| Aantal proefpersonen: | 20 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44634
Bron: ToetsingOnline
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL6143 |
| NTR-old | NTR6298 |
| CCMO | NL61715.018.17 |
| OMON | NL-OMON44634 |

# Resultaten